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CAUSE NO. 19639 & JG 02

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KIM:BERLY D. STUBBLEFIELD, NIDIVIDUALLY, AND AS REPRESENTATIVE OF THE ESTATE OF KEITH JEROME STUBBLEFIELD AND ANYF OF KEITH JEROME STUBBLEFIELD, JR., A MINOR CHILD; KORIETTA LASHAY STUBBLEFIELD, A MINOR CHILD; KENDALL WAYNE STUBBLEFIELD, A MINOR CHILD; AND KEDRIC ROY STUBBLEFIELD, A MINOR CHILD:

Plaintiffs.

Vs.

MERCK & CO., INC.; HARVEY RESNICK, M.D., & R/D CLINICAL RESEARCH, INC.

Desendants

IN THE DISTRICT COURT OF COURT

BRAZORIA COUNTY, TEXAS

3397 JUDICIAL DISTRICT

PLAINTIFF'S ORIGINAL PETITION

COMES NOW KIMBERLY DIANNE STUBBLEFIELD, individually and as next friend of KEITH JEROME STUBBLEFIELD, JR., a minor child, KORJETTA LASHAY STUBBLEFIELD, a minor child, KENDALL WAYNE STUBBLEFIELD, a minor child and KEDRIC ROY STUBBLEFIELD, a minor child. each heirs to the ESTATE OF KEITH JEROME STUBBLEFIELD, Deceased (Plaintiffs), by their anomeys, and for cause of action against Defendants Merck & Co., Inc., Harvey Resnick, M.D., & R/D Clinical Research, Inc., and states as follows:

Discovery Plan Level 2

Plaintiff requests that this lawsuit be governed by Discovery Plan Level 2 pursuant to Rule 190.3 of the Texas Rules of Civil Procedure.

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Parties, Jurisdiction and Venue

Plaintiff, Kimberly Dianne Stubblefield, is the surviving spouse of Decedent, Keith Jerome Stubblefield, and files this suit individually and on behalf of and as next friend of the minor children (named above and herein) of the lawful maniage of Kimberly Stubblefield and Keith Jerome Stubblefield, Decedent, and, in accordance with Rule 44 of the Texas Rules of Civil Procedure and by agreement of all rightful heirs of the estate of Keith Jerome Stubblefield and for their benefit as heirs to the estate of Keith Jerome Stubblefield.

Mrs. Stubblefield is an individual residing in Harris County, Texas. As the surviving spouse of Decedent she has standing to bring a suit for damages due to the wrongful death of her husband. Tex. Civ. Prac. & Rem. Code §71.004 (Texas Wrongful Death Act). Mrs. Stubblefield also has standing to bring a personal injury action on behalf of Decedent pursuant to Tex. Civ. Prac. & Rem. Code §71.021 (Texas Survival Act), which provides that "a personal injury action survives to and in favor of the heirs, legal representatives, and estate of the injured person." By agreement of the lawful heirs, Mrs. Stubblefield meets the requirement to bring this suit because (1) Keith Jerome Stubblefield died intestate, (2) the rightful heirs include Kimberly Stubblefield, Keith Stubblefield, 3r. (D.O.B. 7/22/85). Keriena Lashay Stubblefield (D.O.B. 10/15/86). Kendall Wayne Stubblefield (D.O.B. 9/27/90) and Kedric Roy Stubblefield (D.O.B. 9/27/90), (3) there are no other living heirs (4) no estate has been opened and (5) no administration is necessary pursuant to Texas Probate Code §178(b). Ford Motor Company v. Cammack, 999 S.W. 2d 1 (Tex. App. – Houston [14th Dist.] 1999).

Keith Jerome Stubblefield, Decedent, resided in Harris County, Texas at the time of his death and at all times pertinent to this claim. Kimberly Stubblefield is the surviving spouse of Keith Jerome Stubblefield and mother of each of his surviving children.

At all times relevant herein, Defendant, Merck & Co., Inc. (Merck), was and is an American pharmaceutical company incorporated under the laws of the State of New

lersey with its principal place of business at One Merck Drive, P. O. Box 100, Whitehouse Station, New Jersey. This defendant may be served with process by and through its registered agent, CT Corporation System, 350 N. St. Paul Street, Dallas, Texas 75201. Defendant was and is in the business of profiting from the design, manufacture, marketing, distribution and/or sales of the brand-name prescription drug Vioxx (rosecoxib).

Desendant, Harvey Resnick, M.D., is an individual licensed to practice and does practice medicine in the State of Texas, Brazoria County, Texas. Dr. Resnick can be served with service of process at his place of business, R/D Clinical Research, Inc., 135 Oyster Creek Drive, Lake Jackson, Texas 77566.

Defendant, R/D Clinical Research, Inc., is a Texas corporation incorporated in approximately 1993 and in good standing and which, at all times relevant to this action, maintained its principal place of business in Lake Jackton, Brazoria County, Texas, and may be served at its principal place of business through its registered agent for service of process and principal director, Sherry Dechert, 135 Oyster Creek Drive, Suite V, Lake Jackson, Texas 77566.

Venue and Jurisdiction

The Coun has venue over this cause of action because it is brought in Brazoria County, the county in which all or a substantial part of the events or omissions giving rise to the claim occurred. See Tex. Civ. Pric. & Rem. Code Ann. § 15.002(a)(1)(Vernon 1998). The goods and services at issue were sold and provided in Brazona County, Texas. Id. at §§ 15.002(a)(1), 15.033. Venue is further proper in Brazonia County pursuant to Tex. Crv. Prac. & REM. Code ANN \$5 71,002 and 71,003. Further, venue is proper in Brazoria County, Texas against defendants Harvey Resnick, M.D. and R/D Clinical Research, Inc. because they each reside in and/or maintain a principal place of business in Brazoria County, Texas. Id. at § 15.003(a)(i). Venue is therefore proper as to all defendants because all of Plaintiff's claims against defendants arise out of the same

transaction, occurrence, or series of transactions or occurrences. See American Home Products Corp., et al., v. Clark et al., 38 S.W. 3d 92 (Tex. 2000). Maintaining venue in Brazoria County, Texas, does not unfairly prejudice any party to this suit; Brazoria County, Texas is a fair and convenient forum for all parties.

This Coun has subject matter jurisdiction over the controversy because the damages are within the jurisdictional limits of the Court. The Court has in personam jurisdiction over defendant Harvey Resnick, M.D., because he is licensed to practice medicine and does practice medicine in Brazoria County, Texas. The Court has in personam jurisdiction over defendant RD Clinical Research, Inc. because it maintains a business in Brazoria County and employs physicians licensed to practice medicine and who do practice medicine in Brazoria County. Texas. The Court has in personam jurisdiction over defendant Merck & Co., Inc., because it has done and continues to do business in Texas, has committed a tort, in whole or in part, in Texas, has continuing contacts in Texas and is amenable to service by a Texas Court. This suit is not removable to federal court under 28 U.S.C. § 1441(b). This is not an action related to "health care" or a physician-patient relationship pursuant to Article 4590i, Texas Medical Liability and Insurance Improvement Act.

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Each Defendant may be liable in one or more of a number of capacities including, but not limited to, the following:

- (1) Manufacturing Defendants. Manufacturing defendants are those defendants involved in the design, manufacture, testing, and marketing of the product at issue in this lawsuit.
- (2) Retailer, wholesaler, or distributor of the product at issue in this lawsuit including without limitation by sampling programs.
- (3) Licensee. A Licensee defendant is one who has manufactured, marketed, or distributed into the stream of commerce the product at issue in this lawsuit.

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- (4) Parent corporation. A parent corporation may be liable for the tortious conduct of its subsidiary corporation when the legal distinctions between the parent corporation and subsidiary corporation are fictinious or should be otherwise disregarded. Additionally, any defendant named as a parent corporation may be individually liable for its own fortuous conduct.
- (5) Successors in interest to another corporation. Successors in interest to another corporation may be liable for that corporation's debts and obligations for many reasons including, but not limited to, express or implied assumption or continuation of the predecessor corporation.
- (6) Agency. Where one or more Defendants, and their employees, officers, and/or representatives were at all times acting as the authorized agent of another Defendant which, as the principal with knowledge of the acts of its agents, is responsible and liable for all the tortious acts of the agent relating to the tires and/or vehicle at issue in this suit.
- (7) Co-conspirators. Where two or more Defendants have entered into an agreement and combined to commit actionable torus and to damage Plaintiffs by such acts or omissions relating to the product at issue in this suit, those Defendants are liable as co-conspirators.

Common Factual Allegations

This action arises from the sales and efficacy of Vioxx, an osteoarthritis and painrelief drug containing refecoxib.

Defendant, Merck & Co., Inc. ("Merck") obtained FDA approval on Vioxx in approximately May of 1999 and began its distribution and sale throughout the United States in approximately May of 1999. Vioxx is a brand name used by Merck to market and distribute references.

Plaintiff Decedent, Keith Jerome Stubblefield, age 37, was given samples of Vioxx and a prescription for Vioxx 50 mg, once per day on February 6, 2001, for back

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pain. Decedent ingested the Vioxx as prescribed through and including March 18, 2001, when Decedent suffered an acute myocardial infarction while washing his vehicle. After being declared brain-dead by two physicians at Spring Branch Hospital, life support was withdrawn and Mr. Stubblefield was pronounced dead with the primary cause of death as sudden oreset acute myocardial infarction.

Desendant Merck distributed and sold Vioxx to consumers such as Decedent. This rolecoxib was approved for marketing based on information in the New Drug Application, which was on a fast-track 6-month approval process to FDA.

Despite knowledge in its clinical trials and post-marketing reports, studies and information relating to cardiovascular-related adverse health effects, Defendants promoted and marketed Vioxx as safe and effective for persons such as Plaintiff.

From approximately 1993 to present or significant portions thereof, Dr. Resnick was a primary investigator and/or independent contractor and/or the agent of Merck and conducted studies in humans prior to and material to Metck's initial marketing and continued marketing of Vioxx. Such studies, including without limitation protocols 058 and 121, were integral to the launching of Vioxx and form the basis for representations by Metck and/or its agents to the relevant medical and consumer community regarding Vioxx.

from approximately 1993 to present or significant portions thereof. Defendant ND Clinical Research, Inc., conducted studies in Brazotia County, Texas, and provided sub-investigators including without limitation Dr. Oscar Oandasan, Dr. Rajesh Dalal, Dr. Irvin Sabrusula. Dr. Aikesh Amin, Dr. Carol Ann James, Dr. Gerald Butterfield, Dr. F.J. Hoffman and Dr. Brian Feaver. Such studies, including without limitation protocols 058 and 121, were integral to the launching of Vioxx and form the basis for representations by Merck and/or its agents to the relevant medical and consumer community regarding Vioxx. At all times relevant hereto, Merck had Clinical, Medical and/or Stalistical Monitors who reviewed and assisted Defendants' in determination of what constituted an

adverse event or serious adverse event related to the study drug, rosecoxib. Merck submitted Dr. Resnick and R/D Clinical Research, Inc. as primary and sub-investigators respectively for human testing on rosecoxib. Dr. Resnick and the team of sub-investigators at R/D Clinical Research, Inc., were provided with an Investigator's Brochure by Merck, which outlined the criteria for the studies. In the studies, cardiovascular adverse events were reported with sufficient pattern to demonstrate drug-related toxicity but were deemed by Desendants as not related. In making these determinations, Merck's employees made site visits to Dr. Resnick and R/D Clinical Research, Inc. at their principal place of business in Lake Jackson, Brazoria County, Texas on at least 65 separate occasions from 1996 through approximately 2000.

Defendants concealed the serious cardiovascular risks associated with Vioxx because a successful inunch of Vioxx was viewed as critical for Merck and safety concerns over hypertension, edema and/or cardiovascular events would have drastically impacted Merck's positioning in the market as compared to its competition drug. Celebrex (celecoxib) placed into the market by Merck competitors Pharmacia and Pfizer some 3 months prior to the launch of Vioxx.

Merck knowingly chose to place these adverse health risks on its consumers despite its knowledge at product launch and in post-marketing data thereafter that use of Vioxx carried significant risk factors. These adverse effects were realized in adverse event reports, in clinical trials where such events were adjudicated by primary investigators with Merck's assistance, and in one or more studies shortly after market launch which showed statistically significant increases in adverse cardiovascular events among Vioxx users including strokes.

In industry sponsored studies presented at the European United League Against Rheumatism (EULAR), an organization in which Merck is a member and corporate sponsor, in June of 2000, it was shown that Viexx use resulted in a statistically significant increase in hyperension, and myocardial infarction. Merck did nothing to

further accurately publish these studies, which were again reported and denied by Merck as to the hypertension problems in the official publication of the American Pharmaceutical Association, Pharmacy Today, Spin War Aside, Lessons Emerge From COX-2 Trials, in August 2000, page 3.

Merck continued to deny the ill health effects associated with Vioxx while at the same time reaping the profits obtained through the non-disclosure. Merck engaged in a massive advertising and sampling program and gained continued increases in market share, which enhanced Merck's financial stability to the detriment of its consumers. The resultant effect to Merck in concealing and failing to reveal and warn of the risks was a more than \$2 billion profit in 2000 alone to Merck and an approximately 23 percent share of the market.

The profits to Merck were realized as it continued to withhold relevant data from Plaintiff and the health care industry generally. For example, in November of 2000, Merck caused the publication of a study in the New England Journal of Medicine and knowingly downplayed and/or withheld from this publication the severity of cardiovascular risks associated with Vioxx consumption over naproxen consumption.

On or about August 29, 2001, the Journal of the American Medical Association published a peer-reviewed human epidemiologic study by the Cleveland Clinic Foundation, Cleveland, Ohio, Dr. D. Mukherjee, et al., showing what Merek had concealed -- that the relative risk of developing a "confirmed adjudicated thrombotic cardievascular event" (defired in the article as "myocardial infarction, unstable angina, cardiac thrombus, resuscitated cardiac arrest, sudden or unexplained death, ischemic stroke, and transient ischemic attacks") among Vioxx users in Merck's trials at a 95% confidence interval ranged from 2.2 for event-free survival analysis, 2.38 compared to resproxen users, and 4.89 for developing serious cardiovascular events among aspininindicated patients. See Mukherjee, D., et al., Risk of Cardiovascular events Associated With Selective Cox-2 Inhibitors, J.A.M.A. 286:8, 954-959, Aug. 22/29, 2001. In addition,

the annualized myocardial Infarction rates for Vioxx users compared to place be revealed a statistically significant increase among Vioxx users. Id.

In the JAMA study the authors set forth the theory that "by decreasing PGh production (Vioxx) may tip the natural balance between prothrombolic thrombosone As and antithrombolic PGh, potentially leading to an increase in thrombolic cardiovascular events." Id. at 957. In a follow-up peer-reviewed study reported in the Journal of the American College of Cardiology on or about February 6, 2002, Dr. Richard J. Bung conducted scientific testing and confirmed that the Cox-2 inhibitor "tips the balance of prostocyclin/thromboxane in favor of thromboxane, leading to increased vascular and thrombotic events." Bing, R., & Lomnicka, M., Why Do Cyclo-Oxygenase-2 Inhibitors Course Cordiovascular Events?, J.A.C.C., 39:3, Feb. 6, 2002.

In responsive Merck-authored studies, Merck set forth the theory that naproxen had a cardioptotective effect and therefore accounted for the cardiovascular risks among Vioxx users. However, this theory was debunked in approximately January of 2002, by a Vanderbilt University School of Medicine human epidemiologic peer-reviewed study published in The Lancet concluding that there is an absence of a protective effect of neproxen or other non-aspirin non-steroidal anti-inflammatory drugs on risk of coronary heart disease. Ray, W., et al., Non-steroidal anti-inflammatory drugs and risk of serious coronary heart disease, an observational cohort study, The Lancet, 359:118-123, Jan. 12, 2002.

In approximately September of 2001 Merck received a rare third Warning Letter from FDA stating in part that defendant's "promotional activities and materials...are false, lacking in fair balance, or otherwise misleading in violation of the Federal Food. Drug, and Cosmetic Act (the Act) and applicable regulations." The FDA stated that defendant's campaign minimized "potentially serious cardiovascular findings" from a Vioxx study and misrepresented Vioxx's "safety profile." The FDA concluded that defendant's claim that "Vioxx has a 'favorable safety profile' is simply

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incomprehensible given the rate of MI [myocardial infarction] and serious cardiovascular events compared to paproxen." (emphasis added).

At all times relevant to this litigation, Defendant Merck had a significant market share based upon claims of Vioxx's efficacy, a very aggressive marketing program which involved financial incentives to sales teams, infusion of some 700 new sales representatives, and a massive advertising and sampling program.

As a result of such marketing, Vioxx gained a significant market share in competition with Celebrex that Merck would not have gained if Merck had not suppressed information about Vioxx and/or made false representations of Vioxx's superiority and efficacy.

If Defendant had not engaged in this conduct, consumers, including Decedent, would have switched from Vioxx to safer products or refrained wholly from its use.

From approximately 1999 through present, Defendant continued to engage a common scheme in marketing, distributing and/or selling Vioxx under the guise that it was safe and efficacious for persons such as Plaintiff before, during and after Decedent experienced this confirmed adverse cardiovascular event resulting in his death at age 37 leaving behind a wife and four minor children.

Plaintiffs allege that the suppression of this information constituted a common scheme by Defendants to conceal material information from Plaintiffs.

Plaintiffs allege that the marketing strategies, including without limitation the detail and sampling programs and direct-to-constimer advertising, of the Defendant targeted Decedent to induce Decedent to purchase Vioxx. At the time the Defendant distributed, manufactured and marketed Vioxx, Defendant intended that Decedent would rely on the marketing, advertisements and product information propounded by Defendant.

Count One - Negligence

Plaintiff restates each and every preceding allegation of this Petition and incorporates each by reference as though set forth in full herein.

Vioxx:

- E. Failed to adequately warn Plaintiff that Vioxx should not be used in conjunction with any risk factors for these adverse effects such as smoking;
- h. Failed to adequately disclose and warn Plaintiff that he undertook the risk of adverse events and death as described herein;
- i. Failed to adequately and timely inform the health care industry of the risks of serious personal injury and death from Vioxx ingestion as described herein.

Defendants knew or should have known that Vioxx caused unreasonably congerous risks and serious side effects, including death, of which Plaintiff Decedent would not be aware. Defendant Merck nevertheless advertised, marketed, sold and distributed the drug knowing that there were safer methods and products.

As a direct and proximate result of the negligence and breach of Defendants, Plaintiff Decedent sustained serious injury and death. Defendants either owed a duty to Plaintiffs or are liable for the tort of negligent undertaking pursuant to Sections 323 and 324A of the Restatement (Second) of Torts. Defendants undertook to provide services for others and therefore had a duty to use reasonable care in the provision of said services. Defendants' assumption of the duties proximately caused Plaintiffs' injuries, Decedent's death, and damages.

Count II - Strict Liability

Plaintiff Decedent ingested Vioxx, a medication that was either manufactured, distributed, sold, prescribed and/or otherwise put into the stream of commerce by the Defendant Merck. Plaintiffs would show that the defective condition of Vioxx rendered it unreasonably dangerous, and that said Vioxx was in this defective condition at the time it left the hands of the Defendant.

The Defendant engaged in the manufacture, distribution, sale and/or prescription of pharmaceutical medications and the Vioxx, without substantial change in the condition in which it was sold, was a proximate cause of Plaintiff's injuries.

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Plaintiffs were unaware of the significant hazards and defects in the Vioxx medication. Therefore, the Vioxx medication was unreasonably dangerous in that it was more dangerous than would be reasonably contemplated by the ordinary user. During the periods that Plaintiff Decedent was taking Vioxx, the medication was being utilized in a manner which was intended by Defendant.

Defendant designed, manufactured and/or placed into the stream of commerce the product, which reached Plaintiff Decedent in the same or substantially the same condition in which it was sold. Upon purchase by Plaintiff Decedent, the product in question was represented to be safe and free from latent defects.

Defendant is strictly liable to Plaintiffs for designing, manufacturing, and placing into the stream of commerce the product which was unreasonably dangerous for its reasonably foreseeable uses at the time it less the control of Defendant because of the design defects which were a producing cause of the occurrence in question.

The product in question was defectively marketed by Defendant with respect to its failure to warn, adequately warn, or instruct in the safe use of the product and such defect was a producing cause of the occurrence in question.

Plaintiffs, therefore, invoke the Doctrine of Strict Liability, Section 402A.

Restatement (Second) of Torts, and as adopted by the Supreme Court of Texas.

Defendant was negligent in the design and marketing of the product in question. Defendant knew, or in the exercise of ordinary care should have known, that the product was defective and unreasonably dangerous to those persons likely to use the product for the purpose and in the manner for which it was intended to be used. Defendant was negligent in the particulars set forth in this and the preceding paragraphs and such negligence was a proximate cause of the occurrence in question.

Defendants owed Plaintiffs the duty of reasonable care when they tested, designed, manufactured, and marketed the product in question. Defendants Violated their duty and were negligent in the particulars set forth herein.

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Defendant Merck is also strictly liable to Plaintiffs under Section 402B of the Restatement (Second) of Torts in misrepresenting to the public that its product was sale and without defect, which statement and representation was false and involved a material fact concerning the character or quality of the product in question, and upon which representations the consumer constructively relied, and which constituted a producing eause of the injury at issue.

Further, each of the above and foregoing acts or omissions of Defendants were more than momentary thoughtlessness, inadvertence, or error of judgment. Such acts or omissions constituted such an entire want of care as to establish that the acts or omissions were the result of actual conscious indifference to the rights, safety, or welfare of the person or persons affected. Trans. Ins. Co. v. Moriel, 879 S.W. 2d 10 (Tex. 1994), citing Tex. Civ. Prac. & Rem. Code Ann. § 41,001(5) (Vernon Supp. 1994). Plaintiffs are entitled to recover judgment against Defendants for exemplary damages.

COUNT III - Misrepresentation and Suppression Of Defendants

Plaintiffs reallege and incorporate herein the foregoing allegations of this Petition.

Defendants misrepresented to Plaintiffs and health care industry the safety and effectiveness of Vioxx and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of Vioxx.

Defendants made misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that Vioxx had defects, dangers, and characteristics that were other than what the defendants had represented to Plaintiff Decedent and the health care industry generally. Specifically, Defendants misrepresented to and/or actively concealed from Plaintiffs, the health care industry and consuming public that:

a. Vioxx had statistically significant increases in cardiovascular side effects, including with limitation myocardial infarction and sudden onset death, as identified

berein which could result in serious injury or death;

- There had been insufficient and/or company-spun studies regarding the safety and efficacy of Vioxx before and after its product launch;
- Vioxx was not fully and adequately tested for the cardiovascular side effects at issue herein;
- Other testing and studies showed the risk of or actual serious adverse risks; and/or that
- There was a greatly increased risk of such cardiovascular events and death; there was a confirmed mechanism by which these thrombotic or curdioviscular events occurred as reported in the scientific literature.

The misrepresentations of and/or active concealment alleged were perpenuted directly and/or indirectly by Defendants.

Defendants knew or should have known that these representations were false and made the representations with the intent or purposed that Plaintiff would rely on them, leading to the use of Vioxx.

At the time of Defendants' fraudulent misrepresentations, Plaintiff Decedent was unaware of the falsity of the statements being made and believed them to be true. Plaintiff Decedent had no knowledge of the information concealed and/or suppressed by Desendant.

Plaintiff Decedent justifiably relied on end/or was induced by the misrepresentations and/or active concealment and relied on the absence of safety information which the Defendants did suppress, conceal or failed to disclose to Plaintiff's detriment.

Defendant had a post-sale duty to wam Plaintiffs and the public about the potential risks and complications associated with Vioxx in a timely manner.

The misrepresentations and active fraudulent concealment by the Defendants constitutes a continuing tort against Plaintiff Decedent, who ingested Vioxx.

Defendants made the inferpresentations and actively concealed information about the defects and dangers of Vioxx with the intention and specific desire that Plaintiffs, health care professionals and the consuming public would rely on such or the absence of information in selecting Vioxx as treatment.

As a direct and proximate result of the fraudulent acts and emissions, suppression and misrepresentation of Defendant, Plaintiffs suffered significant and ongoing injury and damages.

Count IV - Breach of Warranty Of Merck & Co., Inc.

Plaintiff restates each and every preceding allegation of this Petition and incorporates each by reference as though set forth in full herein.

When Defendant placed Vioxx into the stream of commerce, Defendant knew of the use for which it was intended and expressly and impliedly warranted to Plaintiffs that use of Vioxx was a safe and acceptable means of treatment.

Plaintiffs reasonably relied upon the expertise, skill, judgment and knowledge of the Defendant and upon the express and/or implied warranty that Vioxx was of merchantable quality and fit for use as intended.

Vioxx was not of merchantable quality and was not safe or fit for its intended use because it was and continues to be unreasonably dangerous and unfit for the ordinary purposes for which it is used in that it caused injury and death to Plaintiff Decedent. Merck breached the warranty because Vioxx was unduly dangerous in expected use and did cause undue injury and death to Plaintiff Decedent.

As a direct and proximate result of Defendant's breach of the warranty of merchantability, Plaintiffs sustained serious and permanent injuries.

Proper notice was provided to Defendant pre-suit by certified mail, return receipt requested.

Count Y - Conspiracy

Defendants engaged in a civil conspiracy or conspiracies and are thus liable to

Plaintiffs for exemplary damages due to their intentional tortuous conduct as pled in this Petition. In addition to the intentional tortuous conduct outlined herein, which in and of itself constitutes civil conspiracy and renders Defendants liable to Plaintiffs for exemplary damages, conspiracy to market a known unreasonably dangerous product and conceal the dangers from consumers constitutes civil conspiracy under Texas law. At the time of the conspiracy, Defendants were aware of the potential harm to Plaintiffs and other similarly situated individuals, as well as Defendants' wrongful conduct. Plaintiffs were injured as a result of Defendants' conspiracy.

Count VI - Actual and Constructive Fraud

Defendants committed actual fraud by making material representations, which were false, knowing that such material representations were false and/or with reckless disregard for the truth or falsity of such material representations, with the intent that all Plaintiffs rely on such material representations; Plaintiffs acted in actual and justifiable reliance on such material misrepresentations and were injured as a result.

In addition, and in the alternative if necessary, Defendants knowingly omitted material information, which omission constitutes a positive misrepresentation of material fact, with the intent that all Plaintiffs rely on Defendants' misrepresentations; Plaintiffs acted in actual and justifiable reliance on Defendant's representations and were injured as a result.

Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiffs relating to the Vioxx at issue in this lawsuit, said breach or breaches constituting fraud because of their propensity to deceive others or constitute an injury to public interests or public policy.

Count VII - Wrongful Death

Defendants are liable, jointly and severally, to the Plaintiffs for the wrongful death of Keith Jerome Stubblefield because the injury that lead to his death was caused by the Defendants or their agents' or servants' wrongful act, neglect, carelessness,

OFFICE OF THE SECRETARY

unskillfullness, and/or default. Tex. Civ. Prac. & Rem. Cope § 71.002(b).

Count VIII - Survival Action

Defendants are liable, jointly and severally, to the estate of Keith Jerome Stubblefield for the personal injuries and associated pain and anguish caused by the Defendants, as outlined in one or more of the foregoing paragraphs. Tex. Civ. Panc. & Rem. Code § 71.021.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, as well as all costs of this action.

Praver For Relief

Plaintiff prays that a judgment be entered in favor of Plaintiffs in such aggregate sum as will fairly and reasonably compensate Plaintiffs for damages arising out of Defendants' conduct as described herein. The conduct of Defendants, as alleged herein, was a direct, proximate and producing cause of the damages to Plaintiffs and of the following general and specific damages:

- (A) Damages to punish Defendants for proximately causing Plaintiffs' injuries;
 - (B) Reasonable attorneys fees and costs;
 - (C) Plaintiff seeks compensatory, punitive and exemplary damages;
 - (D) Physical pain and suffering of Plaintiff Decedent;
 - (E) Mental anguish of Plaintiffs;
 - (F) Medical and Counseling expenses;
 - (G) Loss of Companionship and Society of Plaintiffs;
 - (H) Funeral Expenses;

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- (1) Pre and post-judgment interest at the lawful rate; and/or
- (J) Such other applicable damages as the Coun deems appropriate.

Plaintiffs bring this suit within two (2) years of the date of death and of discovering his Vioxx-related conditions or the existence of any Vioxx-related causes of

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action.

JURY DEMAND

PLAINTIFFS DEMAND THAT ALL ISSUES OF FACT IN THIS CASE BE TRIED TO A PROPERLY IMPANELED JURY.

Respectfully submitted,

THE LANIEBLAW FIRM

BY:

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ATTORNEYS FOR PLAINTIFF

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DFFICE OF THE SECRETARY

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KIMBERLY D. STUBBLEFIELD, INDIVIDUALLY, AND AS REPRESENTATIVE OF THE ESTATE OF KEITH JEROME STUBBLEFIELD AND ANY OF KEITH JEROME STUBBLEFIELD, JR., A MINOR CHILD; KORJETTA LASHAY STUBBLEFIELD, A MINOR CHILD; KENDALL WAYNE STUBBLEFIELD, A MINOR CHILD; STUBBLEFIELD, A MINOR CHILD; STUBBLEFIELD, A MINOR CHILD;

Plaintiffs,

Vs.

MERCK & CO., INC.; HARVEY RESNICK, M.D., & RVD CLIMICAL RESEARCH, INC.

Defendants

IN THE DISTRICT COURT OF STITLE STATE OF S

BRAZORIA COUNTY, TEXAS

239 JUDICIAL DISTRICT

PLAINTIFF'S REQUEST FOR DISCLOSURE TO DEFENDANTS MERCK & CO., INC., HARVEY RESNICK, M.D., & R/D CLINICAL RESEARCH, INC.

- TO Defendant, Merck & Co., Inc., by and through its registered agent for service of process in the State of Texas, CT Corporation System, 350 N. St. Paul Street, Dallas, Texas 75201.
- TO: Defendant, Harvey Resnick, M.D., by service of process at his place of business, 135 Oyster Creek Drive, Lake Jackson, Texas 77566.
- TO: Defendant, R/D Clinical Research, Inc., through its registered agent for service of process. Sherry Dechen, 135 Oyster Creek Drive, Suite V, Lake Jackson, Texas 77566.

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Pursuant to Rule 194, you are requested to disclose, within 50 days of service of this request, the information and/or material described in Rule 194.2(a), (b), (c), (d), (c), (f), (g), (h), (i), (j) and (k).

Respectfully Submitted.

THE LANGER LAW FIRM

BY:

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GOFORTH LEWIS LLP Carlene Rhodes Lewis TSB #16821600 Shelly A. Sanford TSB #00784904 2200 Heritage Plaza 1111 Bagby Houston, Texas 77002 Tel. (713) 650-0022 Fax (713) 650-1669

ATTORNEYS FOR PLAINTIFF



FAX

From:	JOANNE LAHNER
Department:	OFFICE OF GENERAL COUNSEL
Location/Mail Drop:	UG4A∠0
Telephone:	267-305-6331
Date	04/08/02
To.	Ted Mayer
Telephone:	
Fax:	212-837-6303
Total number of pages:	26
Subject:	new lawrent

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FACSIMILE COVER LETTER

Confirmation copy to follow under separate cover:

YES: NO:

OFFICE OF THE SECRETARY

MERCK & CO., INC.

[CALLED PENNEY AND SHE SAID NOT TO FAX THIS.]

ONE MERCK DRIVE

PO BOX 100 .

WHITEHOUSE STATION, NJ 08889-0100

FAX: (908) 735-1224

DATE:

MAY 24, 2002

TO:

Nama:

GERRY BERWICK

Company/Firm:

UG-LEGAL

Fax No .:

267-305-0045

FROM:

Name:

BETTY L. GOOD

Location: Office Phone No.: OFFICE OF THE SECRETARY

908-423-4043

Number of Pages (Including Cover Page): 25

SUBJECT:

Kimbarly D. Stubblefield, et al. v. Marck & Co., Inc., et al.

Attached is a Pelition and Plaintiff's Request for Disclosure in connection with the subject case re alleged wrongful death from Vioxx.

The hard copy of said documents will be sent to you via overnight shuttle.

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Service of Process Transmittel Form
Datas, Texas

05/22/2002

Via Federal Express (2nd Day)

TO: Debra A Bollwage Assistant Secretary Alarce & Co., Inc. One Merck Drive Whitehouse Station, NJ 08889-0100

> Phone: (908) 423-1688 ex: FAX: (908) 735-1224

EMAIL: DEBRA_BOLLY/AGE@MERCK.COM

OFFICE OF THE SECRETARY

RE: PROCESS SERVED IN TEXAS

FOR March & Co., Inc. Domestic State; NJ

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY ACENT OF THE ABOVE COMPANY AS FOLLOWS:

I TITLE OF ACTION.

Kimberly D. Stubblefield et al vs Marck & Co. Inc. et al

2. DOCUMENTIST PLAVED:

Chavon, Origina, Pention, Request for Disclosure

J. COURT:

239Th Judicial District Court Brazorta Caunty Taxas

Casa Number 19489 "JGO2

4. NATURE OF ACTION

Wrongful death alleging from Vioxx

3. ON WHOM PROCEER WAS SERVED.

CT Corporation System, Dallas, Toxas

S DATE AND HOUR OF LERYICE

By Process server on 05/22/2002 at 10:30

T. AFTERBANCE OR ANEWER BULL

10:00 a.m. Manday next after expiration of 20 days (Citation) 50 days

[Request for Disclosure)

& ATTORNEYESIS

Patrick N Heines 1231 Lamer Ste 1550

Houston, TX 77010

1. REMARAS:

CC: Frances Stangota Secretary

Marck & Cc., Inc. One Marck Dilve PO Box 100 WSJAB-06

Whitehouse Station, NJ 08889-0100

EMAIL: FRANCES_STANGOTA@MERCK.COM

Information complies on this continuing form its recovered for C.T. Corporation. System's recognitive groups and the permit buck retrained for recogniting a control of the permit buck retrained action, the amount of samigate, the seasonal data, or any information that can be always from the decuments theorytimes. The racio and a retrained for corporating the documents and for taking the appropriate action.

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C. Siziar

Service of Process Transmittal Form Dallas, Taxas

05/22/2002

CT Corporation System SIGNED

MIT

KASEY L. McGoo LOOREXL

350 Korth St. Paul Street Dalles, TX 75201 SOP WS 0004508773

information continues on this parameter form is recorded for C.Y. Carperation System's record. Emeny discrepants and the james cutch information that exceeds the member date and constitute a legal pointer at the nature of action, the amount of compate, the ancient state, or any information that can be obtained from the decommon theorems. The recovered incommon termination of the decommon and for taking the appropriate action.

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#### CASE #19689\*JG02

THE STATE OF TEXAS

CITATION

TO: MERCK & CO., INC. THROUGH ITS AGENT FOR SERVICE C.T.

CORPORATION

350 N. ST. PAUL STREET DALLAS, TX. 75201

DEFENDANT

NOTICE:

YOU HAVE BEEN SUED. You may employ an anomey. If you or your attorney do not file a written answer with the clerk who issued this citation by 10:00 A.M. on the Monday next following the expiration of twenty days after you were served this citation and PLAINTIFF'S ORIGINAL PETITION AND REQUEST FOR DISCLOSURE, a default judgment may be taken against you. Said answer may be filled by mailing same to: Dismitt Clerk's office, 111 E. Locust, Sie. 500, Angleton, TX 77515-4678 or bringing it to the office. Our street address is 111 E. Locust, and we are located on the Fifth floor of the Courthouse in Room 500.

The case is presently pending before the 239TH District Court of Brazonia County sitting in Angleton, Texas, and was filed on the 2ND day of MAY, 2002. It bears cause number 19689 JG02 and Styled:

KIMBERLY D. STUBBLEFIELD, ET AL Plaintiff.

and MERCK & CO., INC., ET AL , Desendant.

The name and address of the attorney filing this action (or party, if pro se') is PATRICK N HAINES, THE LANGER LAW FIRM, 1331 LAMAR, STE. 1550, HOUSTON, TX. 77010.

The nature of the demands of said Plaintiff is shown by a true and correct copy of Plaintiff's Petition accompanying this citation

Issued under my hand and the seal of said court, at Angleton, Texas, this the 3RD day of MAY, 2002.

JERRY DEERE, DISTRICT CLERK BRAZORIA COUNTY, TEXAS

By Ship Toque Deputy

SERVICE COPY

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P435.05

# IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS COUNTY DEPARTMENT, CHANCERY DIVISION LED

MAY 2 0 2002

DOROTHY BROWN CLERK OF CIRCUIT COURT

| ) Civil Action No. 02 CH 09035<br>) Amount Claimed: An amount necessary to<br>) satisfy the jurisdictional requirements of this<br>) court and which is less than \$75,000 for the<br>) named Plaintiff |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ) Plaintiff demands a jury trial )                                                                                                                                                                      |
|                                                                                                                                                                                                         |

# 131 AMENDED CLASS ACTION COMPLAINT

NOW COMES Plaintiff Scott Zeedyk, on behalf of himself and all other persons similarly situated, by and through his attorney, John Nydakis, and Complains of Defendant Merck & Co., inc. ("Norck"), as follows

# A. PARTIES AND VENUE

- Plaintiff by his attorney, brings this Class Action Complaint on his own behalf and on behalf of all others similarly situated to, intervalia, obtain damages from potentially life threatening side effects and diseases caused by the taking of the drug marketed under the brand name "Vioxa" by Defendant Merck
- 2 Plaintiff is a resident and citizen of Stickney, Cook County, Illinois
- 3 Defendant Nierck is a New Jorsey corporation having its principal place of business in New York, New York
- The court has jurisdiction over the Defendant and the matters herein pursuant to 735 ILCS 5/2-209 as Defendant Nerck transacts business within the State Of Illinois on a regular and continuous basis and has made and performed contracts by the sale of Vioxx and other pharmaceutical products within the State of Illinois
- 5 Plaintiff expressly waives any and all rights or claims he may have against Defendant Merch to recover damages, expenses, attorney's fees and costs in the above-captioned case whose sunt total is greater than seventy-five thousand dellars (\$75,000)

# B. CLASS OF PERSONS

- Plaintiff brings this litigation as a class action pursuant to 735 ILCS 5/2-801 to certify a Plaintiff class. Plaintiff brings this action on his own behalf and on behalf of the following Class all persons in the United States, including their successors in interest, who have injected Vionx for approved uses and in approved doses and for unapproved uses and unapproved doses.
- 7 Excluded from the Class are Defendant and its officers and directors.
- 8 <u>Numerosity</u> The Class is so numerous that joinder of all members is impracticable. Thousands of persons, throughout the United States, were and/or are prescribed Vioxx
- 2 Typicality The claims of the representative Plaintiff are typical of the claims of each member of the Class. Plaintiff and all other members of the Class have used and/or continue to use Vienn. Plaintiff has no interests antagonistic to the claims of the Class.
- 16. Adequacy of representation: Plaintiff will fairly and adequately protect and pursue the interests of the members of the Class. Plaintiff understands the nature of the claims herein and his role in these proceedings, and will vigorously represent the interests of the Class. Plaintiff's counsel has experience in consumer class cases and is qualified to pursue this literation for the Class.
- 11 The class action is maintainable. This action is apprepriate for class status because
  - the prosecution of separate actions by or against individual members of the Class would create risk of inconsistent or varying adjudications with respect to individual members of the Class which would establish incompatible standards of conduct for Defendant.
  - (b) Defendent has acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final relief or corresponding declaratory relief with respect to the Class as a whole, and
  - any questions affecting only individual members, and a Class action is superior to other available methods for the fair and officient adjudication of the controversy.

    This class litigation is an appropriate method for the fair and efficient adjudication.

of the claims involved. The size of the expected recovery for an individual Class member is not expected to be substantial enough for any one Class member to incur the costs and expenses of this litigation. There are no foreseeable difficulties likely to be encountered in the management of a class action.

- 13. Commonality. There are issues of fact and law common to the Class, and these questions predominate over any questions affecting only individual Class members. The common questions include, but are not limited to, the following:
  - (a) whether Defendant has failed to adequately warn of the serious cardiovascular tisks and other serious risks associated with the ingestion of Viene:
  - (b) whether an emergency notice and revised patient insert warning of the hazards associated with Vioxx should be disseminated to Class members.
  - (c) whether the Defendant negligently designed, manufactured, warned, marketed and advertised Vioxx.
  - (d) whether Defendant adequately and appropriately tested Vioxy.
  - (c) whether patients who have taken Vioxx are entitled to monorary relief:
  - (f) whether the omissions, misrepresentations or false statements were made intentionally willfully, wantonly recklessly or negligently.
  - (g) whether Defendant nived a duty to the Class members: what is the scope of any duty, and was the duty breached.
- (b) whether the Class members have been damaged and, if so, what is the proper measure of damages:
- (i) whether Viova causes injury to its users:
- (i) whether Merck is strictly hable for sales and distribution of a dangerously defective product:
- (b) whether Merck negligently designed, manufactured, warned about, distributed and marketed Vioxy; and
- (1) whether the serious side effects, injuries and damages from the use of Views support the need for medical monitoring of persons who have used the drug

DOROTHY BROWN - CLERK OF THE CIRCUIT COURT OF COON COUNTY

# C. FACTUAL ALLEGATIONS COMMON TO ALL COUNTS

- 13. At all relevant times hereto. Plaintiff was prescribed and consumed Vioxx for acute pain management. Plaintiff was unaware of the serious risks associated with the taking of Vioxx.
- 14 At all relevant times hereto. Defendant Merc's did or caused Vionk to be manufactured designed tested, packaged, supplied, marketed advertised and sold in the United States
- Vioxx is a non-steroidal anti-inflammatory drug ("NSAID") with a COX-2 inhibitor, which was approved on May 20, 1999, for the treatment of primary dysmenorrhea (menstrual cramps); for acute pain management in adults and for relief of osteourihinis Vioxx reportedly reduces pain and inflammation while also significantly reducing meidents of stomach offers commonly associated with pain relievers such as aspirin and improten
- Traditional NSAIDs such as ibaprofer and espirichiock both COX-2 and COX-1 enzymes. Because the COX-1 enzyme protects the lining of the stomach blocking it can lead to stomach irritation. It is believed that COX-2 inhibitors reduce the incidence of stomach ulcers and bleeding because they do not block COX-1 enzymes.
- 17 There are over 86 million users of Viona nationwide. Annual sales exceed \$2.5 billion for Viona in the United States.
- The Vioxa Gastrointestinal Outcome Research Study (hereinafter "VIGOR"), sponsored by Merck, was designed to gather information regarding "clinically meaningful upper gastrointestinal ("GI") events and to develop a large controlled database for overall safety assessment."
- The VIGOR study included about 8000 patients, 4000 for the Vioxx 50 mg a day treatment group and 4000 for the naproven 1000 mg a day treatment group, for a median time period of nine months. (Naproxen is an NSAID, sold under such brand names as Naproxen and Alexe). The study compared the safety of the two patient groups. The results of the study concerning GI events demonstrated that the group on Vioxx has a significantly lower incidence of GI events, 2.08% compared to Naproxen 4.49%. (G)

DOROTHY BROWN - CLERK OF THE CIRCUIT COURT OF COOK COUNTY - 4

- events include perforations, symptomatic ulcers, and gastrointestinal bleeds)
- The VIGOR study also found that serious cardiovascular events occurred in 101 patients (2.5%) in the Vious group compared to 46 (1.1%) in the Napronen group. In addition, invocardial infarctions (heart attacks) occurred in 20 patients in the Vious group (0.5%) compared to 4 patients in the Napronen group (0.1%)
- According to the Department of Health and Human Services ("HHS"). Defendant Merck engaged in a campaign that minimized the serious cardiovascular findings observed in the VIGOR study. The VIGOR study observed patients on Vionn with a four to five times increase in invocardial infarctions, compared to patients on the NSAID Napresyn (naproxen).
- 22 EHS also cited Defendant Merch for engaging ma promotional campaign that minimized the Vioxx/Coumadin (warfacin) drug interaction, (warfacin is an auticoagulant and the mixing of Vioxx and Coumadin can lead to the potentially serious risk of bleeding), making unsubstantiated superiority claims against other NSAIDs, and promoting Vioxx for unapproved uses and dosing regimens. Hills found Defendant Merch's misrepresentations particularly troubling because of Hills's previous objections to Defendant Merch's misrepresentations.
- According to HHS. Merch's press release of May 20, 2001 entitled "Merch Confirms Far orable Cardiovascular Safety Profile of Vionn," which stated that Vionn has a "favorable cardiovascular profile" was "simply incomprehensible, given the rate of GI and serious cardiovascular events compared to Napronen." HHS concluded that Defendant Merch infinitized the potentially scrious cardiovascular findings of the VIGOR study and minimized the Vionn/Counadin drug interaction.
- After carefully reviewing the results of the VIGOR study, the U.S. Food and Drug Administration ("FDA") agreed with the Authoris Advisory Committee recommendations of February 8, 2001 that the label for Vioxy should include the gastromtestinal and cardiovascular information. Hence, on April 11, 2002, the FDA approved new indication and label changes for Vioxy which included this information.

DOKOTHY BROWN - CLERK OF THE CIRCUIT COURT OF COOK COUNTY 5

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# D. CAUSES OF ACTION

# COUNT I - (Strict Products Liability)

- 25 Plaintiff alleges and incorporates paragraphs I through 24 as if set forth fully above
- 25 Defendant Merck is the manufacturer and/or supplier of Vioxs
- Defendant Merek manufactured and/or supplied Vions, which was defective and hazardous in design and formulation in that, when left in the hands of Merek, the foreseeable risks exceeded the benefits associated with the design or formulation
- 25. Alternatively, Defendant Merck manufactured and/or supplied Vioxy, which was defective or hazardoes in design or formulation, in that, when it left the hands of Merck, it was unreasonably dangerous, more dangerous that an ordinary consumer would expect and more dangerous than other forms of NSAIDs.
- The Defendant Merck manufactured and/or supplied Vioxx, which was defective or hazardous due to inadequate warning or instruction because Merck knew or should have known that Vioxx posed a greater risk to patients taking it than to those patients taking other NSAIDs.
- 30 Defendant Merck failed to adequately test Vioxy before its introduction into interstate commerce. Such tests would have demonstrated that when compared to other NSAIDs patients taking Vioxy had increased risk of cardiovascular events and adverse drug interactions with Coumadia.
- Defendant Merek supplied and/or distributed Vioxs, which was defective due to madequate post-marketing warning or instruction. Defendant Merek knew or should have known that Vioxx increased the risk of cardiovascular events and adverse drug interactions with Counadia, when compared to other NSAIDs.
- As the procuring cause and legal result of the defective and/or hazardous condition of Vioxx as manufactured and/or supplied by Defendant Merck, and as a direct and legal result thereof. Plaintiff and other Class members have been damaged

# COUNT II - (Strict Products Liability - Failure to Warn)

- 33. Plaintiff realleges and incorporates paragraphs I through 24 as if so forth fully above
- 34 Defendant Merck is the manufacturer and/or supplier of Vioxy
- 3.5 Defendant Merck failed to adequately and fully warn of the higher risk of cardiovascular events, of Vioxx/Coumadin interaction, and of unapproved use, when compared to other NSAIDs
- 56. Defendant Merck failed to adequately test Vioxa before its introduction into interstate commerce. Such test would have demonstrated that patients taking Vioxa had increased risk of cardiovascular event and adverse drug interaction with Counadin, when compared to other NSAIDs.
- Defendant Merch supplied and/or distributed Vioxs, which was defective due to inadequate post-marketing warning or instruction. Defendant Merch knew or should have known that Vioxx increased the risk of cardiovascular events and adverse drug interaction with Coumadin, when compared to other NSAIDs.
- As the producing cause and legal result of the defective and/or hazardous condition of Vioxx, as manufactured and/or supplied by the Defendant Merck, and as a direct and legal result thereof. Plaintiff and other Class members have been damaged.

# COUNT III - (Negligence)

- 39 Plaintiff realleges and incorporates paragraphs 1 through 24 as if set forth fully above
- 46 Defendant Merck has had a duty to exercise reasonable care in the manufacture, sale distribution, marketing and warning of Vioxx, including a duty to ensure that Vioxx did not cause users to suffer from unreasonable and dangerous side effects.
- Defendant Merck breached its duty to Plaintiff and members of the Class, to exercise reasonable care in the manufacture, sale, distribution, marketing and warning of Vioxx in that Defendant Merck knew or should have known that Vioxx created an emeasonably high risk of dangerous side effects, including an unreasonably high risk of

DOROTHY BROWN - CLERK OF THE CIRCUIT COURT OF COOK COUNTY | 1

- cardiovascular events and adverse drug interaction with Coumacin, when compared to other NSAIDs.
- 42 Defendant Merck was negligent in the manufacture, sale, testing, distribution, marketing and warning of Vioxx in that it
  - (a) failed to issue reasonable and proper warnings regarding all possible adverse effects associated with the use of Vioxy.
  - (b) failed to conduct adequate pre-clinical testing, clinical testing and post-marketing oversight and surveillance to determine the effect of Vio.xx.
  - (c) failed to provide adequate instruction to health care providers for appropriate risks and uses of Vioxx.
  - (d) failed to warn Plaintiff and the Class, prior to encouraging the use of Viexs, that Viexs increased the risk of cardiovascular events and adverse drug interaction with Cournadio, when compared to other NSAIDs.
  - (e) failed to use reasonable care in the design and manufacturing of Vioxy to avoid and prevene the increased risk of cardiovascular events and saverse drug interaction with Counadin, when compared to other NSAIDs, and
  - (f) was otherwise carcless or negligent
- 43 Defendant Merck knew or should have known that Plantiff and the Class would foresecably suffer injury as a result of Defendant Merck's failure to exercise ordinary care as sot tenth above.
- 44 As the proximate cause of Defendant Merck's negligence, Plaintiff and other Class members have been danfaged.

# COUNT IV - (Breach of Express Warranty)

- 45 Plantiff realleges and incorporates paragraphs. I through 24 as if set forth fully above
- Defendant Merck expressly warranted that Vienx was safe for use by Plentiff and the Class for the treatment of conditions for which Vienx was advertised.
- Weak does not conform to Defendant Merch's express representations because Views does not warn of increased risk of cardiovascular events and adverse drug interaction

DOROTHY BROWN - CLERK OF THE CIRCUIT COURT OF COOK COUNTY IS

with Commadin, when compared to other NSAIDs

18 As a direct and proximate result of Defendant Merck's breach of express warranty.

Plaintiff and other Class members have been damaged

# COUNT V - (Breach of Implied Warranty)

- 19 Plaintiff realleges and incorporates paragraphs 1 through 24 as if set forth fully above
- 50 At the time Defordant Merck manufactured, sold, distributed, and marketed Vioxx. Defendant Merck knew of the use for which Vioxx was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use
- 31 Plaintiff and the Class and their health care providers reasonably relied upon the skill and judgment of Defendant Merck as to whether Vioxx was of merchantable quality, safe and fit for its intended use
- 22 However, despite this implied warranty. Vioux was not of merchantable quality safe for the for its intended use because Vioux was and is unreasonably dangerous and unfit for the ordinary purposes for which it was intended and used
- 55 As a direct and proximate result of Defendant Merck's breach of implied warranty of inorchantability. Plaintiff and other Class members have been damaged

# COUNT VI - (Consumer Fraud)

- 54 Plaintiff realizes and incorporates paragraphs 1 through 24 as if fully set forth above
- At all times relevant hereto and to date there was in force a statute in the State of Illinois 815 ILCS 505 et seq., commonly known as the "Consumer Fraud and Deceptive Practices Act ("Act")." the scope of which covers all of the relevant acts, conduct, practices and transactions noted above and herein
- 56 The Plaintiff and members of the Class are consumers, as defined by the Act of Defendant Merck's product. Vions.
- FF The acts, practices and conduct of Defendant Morek involved trade practices addressed

DOROTHY BROWN - CLERK OF THE CIRCUIT COURT OF COOK COUNTY | 9

to the market generally and/or otherwise implicate consumer protection concerns

- By one or more of the following acts, practices and conduct noted above in Paragraphs 13-24, directly or by implication, Defendant Merck violated said Act and damaged the Plaintiffs and members of the Class by engaging in unfair and/or deceptive acts or practices, and/or engaging in conduct which creates a likelihood of confusion or misinderstanding, in the conduct of their trade or commerce
- 59 That Defendant Merck intended that the Plaintiff and members of the Class rely on its above-mentioned unfair and/or deceptive acts, practices and conduct
- 60. That Defendant Merck's acts, practices and conduct were done knowingly, intentionally, willfully, recklessly, with actual malice, and with a wanton disregard of the rights of the Plaintiff and members of the Class, an especially vulnerable group who are suffering from medical ailments and who are not as educated about pharmaceutical drugs as the Defendant Merck is, and as such the Plaintiff and members of the Class are entitled to punitive, or exemplary, damages
- 61. As a result of said unfair and/or-deceptive acrs, practices and conduct by Defendant Attack and the Plaintiff's and members of the Class' justifiable and reasonable reliance thereupon, the Plaintiff and members of the Class have been damaged
- Should they prevail, the Plaintiff and members of the Class are entitled to reasonable attorney's fees and costs from Defendant Merck in an amount necessary to compensate the Plaintiff and members of the Class for the costs and disbursements of this action pursuant to 815 ILCS 505 et seq..

#### E. PRAYER FOR RELIEF

WHEREFORE, for each and/or any of the above-mentioned Counts, Plaintiff prays for the following relief:

A can order certifying the Class as set forth herein, with the named Plaintiff as class representative and his counsel as class counsel.

DOROTHY BROWN - CLERK OF THE CIRCUIT COURT OF COOK COUNTY 10

- B a declaration that Defendant Nerck's conduct violated the law as alleged in each cause of action:
- C a judgment for Plaintill and the Class for compensatory damages sustained as a result of Defendant Merck's unlawful conduct, including medical, hospital and incidental expenses according to proof.
- Does order requiring Defendant Merck to refund and make restitution of all monies obtained from the sale of Vioxx to the Plaintiff and the Class and to impose a constructive trust on said monies.
- E an order awarding Plaintiff and the Class attorneys' fees, costs and expenses against Defendant Merck as allowed by law.
- if an order against Defendant Merck awarding Plaintiff and the Class an amount necessary to compensate the Plaintiff and the Class for the costs and disbursements of this action, including reasonable attorney's fees, pursuant to 815-11.05-505 et sequ
- Geperstant to 815 ILCS 505 et segl, an order against Defendant Merch awarding Plaintiff and the Class-punitives or exemplary, money damages found to be suitable and sufficient to deter similar acts by Defendant Merch in the future and to punish Defendant Merch for its previous acts, and
- II. such other or further relief as the Court may hold appropriate.

Respectfully submitted.
SCOTT ZEEDYK on behalf of himself and all other persons similarly situated

John Xydakis, Attorney for Plaintiffs

John Xvdakis
Atti No. 36859
Suite 201
125 W. 55<sup>th</sup> St
Chirendon Hills, IL 60514
(630) 215-5515

DOROTEN BROWN - CLERK OF THE CIRCUIT COURT OF COOK COUNTY II

# IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS COUNTY DEPARTMENT, CHANCERY DIVISION

SCOTT AREDYK on behalf of himself and all ) Civil Action No.
other persons similarly situated )
Plaintiffs. ) Amount Claimed: An amount necessary to satisfy the jurisdictional requirements of this court

NERCK & CO. INC )
Plaintiffs demand a jury trial

AFFIDAVIT PURSUANT TO SUPREME COURT RULE 222(B)

Under penalties as provided by law pursuant to Section 1-109 of the Code of Civil Procedure, the undersigned conflict that the statements set forth below are true and correct, except as to matters therein stated to be on information and belief and as to such matter the undersigned certifies as aforesaid that he world believes the same to be true.

1. The total money damages sought for all Plaintiffs in the above-captioned case exceeds life thousand dollars (\$50,000)

FURTHER ATFIANT SAYETH NAUGHT

Defendant.

DOROTHY BROWN - CLERK OF THE CIRCUIT COURT OF COOK COUNTY 12

5005 - SS1 225 BS5

# 33" JUDICIAL DISTRICT COURT FOR THE PARISH OF ALLEN

STATE OF LOUISLAN'A

C2002-020

NO.

DIVISION "

DOCKET NO.

JOHN ABRUSLEY SR.

VERSUS ATRUE & CORRECT COPY OF ORIGINAL FILED: 10111

MERCIC & CO., MOBERIN, LA

JAN 1 1 2002

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HOLEY CHA OF COUNTY

FILED:

DEPUTYCLERK

#### PETITION FOR DAMAGES

The petition of John Abrusley Sr., who is a person of full age of majority, and who is domiciled in this Parish, respectfully represents that:

1.

Made defendants herein are the following:

- A. Merck & Co., Inc. (Merck) is a corporation organized and existing under the laws of the State of New Jersey, and does business in all 50 states, including Louisiana. At all times material, Merck has been regularly engaged in the manufacturing, marketing, sale and distribution of the pharmaceutical Vioxx, which is then sold into interstate commerce in Louisiana, as well as throughout the United States.
- B. John Doe who is a resident of this state and who, at all times relevant hereto, was employed as a detailman and/or salesman for defendant, Merck. The plaintiff will amend/supplement this petition with the specific information concerning this defendant as soon as such information is obtained in discovery.

2.

Plaintiff, John Abrusley Sr. is a resident of this Parish and began experiencing pain in his hip in the summer of this year. He went to see his doctor who gave him an injection of Risticar and gave him samples of Vioxx.

3.

The Vioxx was packaged in a blister pack which contained four 25 mg pills.

4

Mr. Abrusley took the Vioxx as directed for approximately two to three weeks when he began to experience blood in his stool. After noticing the blood in his stool, he stopped taking the Vioxx.

5.

Several days later Mr. Abrusaly went to play golf. He began to feel ill as he was beginning his round and decided to go back home.

6.

Mr. Abrusley returned his clubs to the clubhouse and went to his car where he began to change his shoes.

7.

While changing his shoes he had a stroke, fellover forward and was unable to move and/or get up. He was able to locate his cell phone and called 911.

8.

The paramedies came and transported Mr. Abrusely to Rapides Regional Hospital where he was treated for injuries that resulted from his fall which included a broken wrist.

9.

At Rapides Regional Hospital Mr. Abrusley underwent a MRI which confirmed that be had a stroke. The stroke has subsequently caused a numbers and/or loss of feeling in his left leg and has needed speech therapy.

10.

Mr. Abrusley has had two operations on his wrist and was forced to undergo extensive physical rehabilitation.

11.

The plaintiff's stroke and resulting injuries were the direct and proximate result his ingestion of the Vioxx. He was never warned of the hazardous and dangerous side affects of Vioxx

12.

Vioxx (Refocoxib) is a Cox-2 inhibitor that is/was designed, created, manufactured, labeled. packaged and/or distributed by the defendants.

13.

Defendant, John Doe, is employed as a detailman and/or salesman for defendant, Merck. As a detailman and/or salesman, John Doe has a personal duty to truthfully represent the harmful side effects of the Vioxx.

14.

The defendant Merck employed detailmen such as defendant John Doe for the purposes of distributing product samples, delivering package inserts and to communicate warnings contained in the inserts to the doctors and/or medical facilities in this Parish.

15.

The defendant, John Doe breached his duty to the plaintiff by failing to disclose to the plaintiff and/or his physician of the hazardous and/or dangerous side effects of the Vioxx.

16

At all times relevant hereto, defendants aggressively marketed and sold Vioxx by misleading potential users such as the plaintiff about the dangers cause by Vioxx, and by failing to protect users from the serious dangers that they knew or should have known to result from the use of Vioxx.

17.

The defendants widely and successfully marketed Vioxx in this Parish. The defendants undertook an advertising blitz extolling the virtues of Vioxx in order to induce widespread use of Vioxx. This marketing campaign consisted of advertisements, promotional literature to be placed in the offices of doctors and health care providers and other promotional materials to be provided by potential Vioxx users.

18.

This campaign also provided for the magazine, newspaper, and/or television advertisements that were published and/or distributed in this state and/or distributed in this parish. These advertisements and promotional materials made claims about the effectiveness, safety and superiority of Vioxx by itself and as compared to other pain relief drugs.

19.

The advertising program, as a whole, by affirmative misrepresentations and omissions, falsely and fraudulently sought to create the image and impression that the use of Vioxx was safe for human use, and had sewer side effects and adverse reactions than other methods of pain relief and

#### Count One

# Strict Product Liability

(pursuant to LSA R.S.9:2800.5 et seq.)

24.

Plaintiff incorporates by reference all of preceding paragraphs as if fully set forth herein and further alleges as follows.

The defendants are manufacturers, distributors and/or suppliers of Vioxx

26.

The Vioxx manufactured and/or supplied by the defendants was not accompanied by proper warnings regarding all possible adverse side effects associated with the use of Vioxx and the comparative severity and duration of such adverse effects; the warnings given did not accurately reflect the symptoms, scope or severity of the side effects.

27

The defendants failed to perform adequate testing in that would have shown that Vioxx used individually and/or in combination with other drugs, possessed serious potential side effects with respect to which full and proper warnings accurately and fully reflecting symptoms, scope and seventy should have been made, both with respect to the use of Vioxx individually, and with respect to its use in combination with other drugs.

28.

The defendants also failed to effectively warn users that numerous other methods of pain relief such as ibuprofen and/or acetaminophen should have been their first line and/or their exclusive methods of pain relief.

29.

The Vioxx manufactured and/or supplied by defendants was defective due to inadequate post-marketing warnings or instructions because, after the defendants knew or should have known of the risk of injury from Vioxx they failed to provide adequate warnings to users or consumers of the Vioxx, and continued to aggressively promote the Vioxx.

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30.

Mr. Abrusley sustained severe injuries as the producing cause and legal result of the defective condition of Vioxx as manufactured and/or supplied by the defendants, and as a circuland legal result of the negligence, carelessness, other wrongdoing and action(s) of the defendants described herein.

خ. 31.

The Plaintiff has required reasonable and nepessary health care, attention and services, and has incurred medical, health, incidental and related expenses. He will in the future be required to obtain medical and/or hospital care, attention and services in an amount that is not yet ascertained.

#### Count Two

#### Strict Product Liability

32.

Plaintiff incorporates by reference all of the proceeding paragraphs as if fully set forth herein and further alleges as follows:

33.

The defendants are manufacturers and/or suppliers of Vioxx.

34.

The Vioxx manufactured and/or supplied by the defendants was defective in design or formulation, in that, when it left the hands of the manufacturers and/or suppliers, it was unreasonably dangerous, it was more dangerous than an ordinary customer would expect and more dangerous than other forms of pain relief.

35.

The Vioxx manufactured and/or supplied by the defendants was defective due to inadequate warnings or instruction because the defendants knew or should have known that the Vioxx created a risk of harm to consumers and the manufacturing defendants failed to adequately warn of said risks.

35.

The Vioxx manufactured and/or supplied by the defendants was defective due to inadequate warning and/or inadequate testing.

-6-

**37**.

The Vioxx manufactured and/or supplied by defendants was defective due to inadequate post-marketing warning or instruction because, after the defendants knew or should have known of the risk of injury from Vioxx it failed to provide adequate warning to users or consumers of the Vioxx and continued to promote the product.

38. 🟃

Mr. Abrusley has sustained severe injuries as the producing cause or legal result of the defective condition of Vioxx as manufactured and/or supplied by the defendants, and as a direct and legal result of the negligence, carelessness, other wrongdoing and action(s) of the defendants described herein.

39.

The Plaintiff has required reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses. These injuries will require him to obtain medical and/or hospital care, attention, and services in an amount that is not yet ascertained.

#### Count Three

# Breach of Express Warranty

40.

Plaintiff incorporates by reference all preceding paragraphs as if fully set forth berein, and further alleges as follows:

41.

The defendants expressly warranted that Vioxx was safe, well accepted, and would not present any severe side effects. These warranties induced the Plaintiff into taking the Vioxx.

42

Vioxx did not conform to these express representations because Vioxx is not safe and has high levels of serious side effects, including life threatening side effects such as the stroke experienced by the plaintiff.

43.

Mr. Abrusley has sustained severe injuries as a direct and proximate result of the defendants' breach of these warranties.

#### Count Four Breach of Implies Warranty

44.

Plaintiffincorporates by reference all of the preceding paragraphs as if fully set forth herein, and further alleges as follows:

45.

At the time, the defandants marketed, sold, and distributed Vioxx for use by the plaintiff, the defendants knew of the use for which Vioxx was intended and implied and warranted the product to be of merchaniable quality and safe and fit for such use.

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The plaintiff reasonably relied upon the skill and judgment of the defendants, as to whether the Vioxx was a merchantable quality, and safe and fit for its intended use.

47

Contrary to such implied warranties, Vioxx was not of merchantable quality, or safe or fit for its intended use, because this product was and is unreasonably dangerous and unfit for the ordinary purposes for which it was used as described above.

Count Five
Neeligence
(pursuant to LSA-C.C. Article 2315)

48

Plaintiff incorporates by reference all of the preceding purgraphs as if fully set forth herein, and further allege as follows:

49.

The defendants had a duty to exercise reasonable care in the manufacture, sale and/or distribution of Vioxx into the stream of commerce, including a duty to assure that the Vioxx did not cause users to suffer from unreasonable, dangerous side effects. The defendants failed to exercise ordinary care in the manufacture, sale, testing, quality control, and/or distribution of Vioxx into interstate commerce, in that the defendants knew or should have known that the product Vioxx created high risks of unreasonable, dangerous side effects, some of which, e.g., myocardial infarction and/or stroke could be fatal.

-8-

The defendant John Doe was delegated this personal duty through and by defendant, Merck! Defendant, John Doe, breached this duty, as described above and by failing to advise the plaintiff and/or the plaintiff's physician of the unreasonably dangerous side effects of Vioxx such as the stroke suffered by the plaintiff. The plaintiff was injured as a direct and proximate result of the defendant, John Doe's breach of such duty.

WHEREFORE, plaintiff, John Abrusley Sr., prays that there be a judgment in his favor and against the defendants, Merck & Co., Inc. and John Doe in an amount that will adequately compensate the plaintiff for his injuries, for all costs incurred in the prosecution of the matter, and the for all legal interest from the date of judicial demand until paid.

Respectfully submitted,

The Andry Law Firm, LLC
JONATHANB. ANDRY
610 Baronne Street

New Orleans Louislane 70113 Telephone: 504-586-8899

Facajmüe: 504-585-2788

By:

Jonathan B. Andry (#20081)
Attorney for Plaintiff

#### PLEASE SERVE:

MERCK & CO., INC.
through its agent for service of process
CT CORPORATION SYSTEM
8550 United Plaza Bivd.
Baton Rouge, LA 70809

JOHN DOE

STATE OF HAWAII

2001 NOV 23 PH 3: 23

R. HIGA CLERK

WAYNE D. PARSONS #1685 1406 Colburn Street, Suite 201C Honolulu, Hawaii 96817 Telephone: (808) 845-2211 Facsimile: (808) 843-0100

Attorney for Plaintiffs

# IN THE CIRCUIT COURT OF THE FIRST CIRCUIT

# STATE OF HAWAII

| DONNA MEIFERT JONES, individually and as Personal Representative of the Estate of FRANK NEWTON JONES, JR., also known as Frank N. Jones, deceased,                                                                                                                                                                                                 | ) [<br>)<br>) C                           | O 1 - 1 - 3369 - 11  Product Liability)  OMPLAINT; DEMAND FOR JURY  RIAL; SUMMONS |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|-----------------------------------------------------------------------------------|
| Plaintiffs,                                                                                                                                                                                                                                                                                                                                        | )                                         |                                                                                   |
| MERCK & COMPANY, INC., a corporation; DOE PHARMACEUTICAL COMPANIES 1 through 50, inclusive; DOE PHARMACIES 51 through 100, inclusive; and DOES 101 through 200, inclusive, JOHN DOES 1-10; JANE DOES 1-10; DOE PARTNERSHIPS 1-10; DOE CORPORATIONS 1-10, DOE 'NON-PROFIT' ORGANIZATIONS 1-10, DOE TRUSTS 1-10, AND ROE GOVERNMENTAL AGENCIES 1-10, | )<br>)<br>)<br>)<br>)<br>)<br>)<br>)<br>) | o Trial Date Set                                                                  |
| Defendants.                                                                                                                                                                                                                                                                                                                                        | )<br>)                                    |                                                                                   |

COMPLAINT

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Cito (vital Court s) 11 Carrier

## INTRODUCTION

This case involves the drug Vioxx that was manufactured, sold, distributed and promoted by defendants to capitalize on the need of the public to have a pain-reliever, similar to Ibuprofen, without any of the known Ibuprofen side effects. Defendants misrepresented that Vioxx was a safe and effective way to relieve osteoarthritis, to manage acute pain in adults, and treat menstrual pain, when in fact the drug causes serious medical problems and injuries such as serious cardiovascular events and death.

## GENERAL ALLEGATIONS

1. This is an action for personal injuries and damages brought on behalf of the Plaintiffs who have been prescribed and supplied with, received, and who have taken and ingested and consumed Vioxx as researched, designed, formulated, compounded, tested, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed or otherwise placed in the stream of interstate commerce by Defendant Merck & Company, Inc., Defendant Doe Pharmaceutical companies 1 through 50, Defendant Pharmacies 51 through 100, Defendants Does 101 through 200. This action seeks, among other relief, general and special damages and equitable relief in order to compensate the Plaintiffs for the injuries and losses caused by these drugs, including but not limited to severe cardiovascular events and death.

- 2. The true names or capacities, whether individual, corporate or otherwise, of Defendants Defendant Doe Pharmaceutical Companies 1 through 50, Defendant Pharmacies 51 through 100, and Does 100 through 200, John Does 1-10, Jane Does 1-10, Doe Corporations 1-10, Doe Partnerships 1-10 and Doe Entities 1-10, inclusive, are unknown to Plaintiffs who therefore sue said Defendants by such fictitious names. Plaintiffs believe and allege that each of the Defendants designated herein by fictitious names is in some manner legally responsible for the events and happenings herein referred to and caused damages proximately and foreseeably to Plaintiffs as alleged herein.
- 3. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their conduct constituted a breach of duty.
- 4. There exists, and at all times herein mentioned, there existed, a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants and exerted control over those defendants. Adherence to the fiction of the separate existence of these certain Defendants as any entity distinct from other

certain Defendants will permit an abuse of the corporate privilege and would sanction fraud and would promote injustice.

- 5. The injuries and losses of Plaintiffs were caused by the wrongful acts, omissions, and fraudulent misrepresentations of Defendants, all of which occurred within the State of Hawaii.
- 6. At all times herein mentioned, one or more of the corporate

  Defendants was, and now is, a corporation doing business in the State of Hawaii.
- 7. At all times herein mentioned, one or more of the individual

  Defendants was, and now is a resident of the City and County of Honolulu, State of

  Hawaii.
- 8. At all times herein mentioned, Merck & Company, Inc. and the Doe Pharmaceutical company Defendants 1 through 50, and each of them were engaged in the business of, or were successors in interest to, entities engaged in the business of research, designing, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the drug Vioxx.
- 9. At all times herein mentioned, Merck & Company, Inc. and the Doe Pharmaceutical company Defendants 1 through 50, and each of them, were authorized to do business within the State of Hawaii and did in fact supply the aforementioned products within the State of Hawaii.
- 10. At all times herein mentioned, the officers and directors of Merck & Company, Inc. and the Doe Pharmaceutical Company Defendants 1 through 50 named

herein participated in, authorized and directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said products and thereby actively participated in the tortious conduct which resulted in the physical and emotional injuries and losses described herein.

11. At all times herein mentioned, Defendant Doe Pharmacies and Defendant Doe Pharmacies, and each of them, were engaged in the business of prescribing, formulating, distributing, supplying and selling Vioxx.

#### THE PLAINTIFF

- 12. Plaintiff, Estate of FRANK NEWTON JONES, III, also known as Frank N. Jones, deceased, who resided in the City and County of Honolulu, in the State of Hawaii, died directly and proximately as a result of taking Vioxx.
- 13. Plaintiff, DONNA MEIFERT JONES, who resides in the State of Hawaii is the widow of FRANK NEWTON JONES, JR., also known as Frank N. Jones, and resided with him in Honolulu, Hawaii at the time of his death.

#### THE DEFENDANT

- 14. Defendant Merck & Company, Inc. and Pharmaceutical company

  Defendants manufactured, marketed, sold and distributed Vioxx which was ingested

  by Plaintiff FRANK NEWTON JONES, JR., also known as Frank N. Jones.
- 15. Defendant Doe 1, whose name is presently not known to Plaintiffs, is a sales representative of Defendant Merck & Company, Inc. who resided in the State of

Hawaii at all times relevant hereto and who promoted and marketed Vioxx for profit on behalf of Defendant Merck & Company, Inc. to healthcare providers in the State of Hawaii.

16. Defendant Doe Pharmacies are business entities that prescribed and/or provided Vioxx to plaintiffs.

17. Defendant Merck & Company, Incorporated is in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale Yioxx.

18. Defendant Merck & Company, Inc. was and is an American pharmaceutical company, incorporated under the laws of the State of New Jersey, whose principal place of business is One Merck Drive, P.O. Box 100, Whitehouse Station, New Jersey, that at all times relevant manufactured and marketed, sold and distributed Vioxx.

#### **EACTUAL ALLEGATIONS**

19. At all times relevant, Defendants, and each of them, themselves, or by and through the use of others, did manufacture, create, design, test, label, distribute, supply, prescribe, market, sell, advertise, warn, and otherwise distribute in interstate commerce and in the State of Hawaii and the State of California, the pharmaceutical product known as Vioxx.

20. Vioxx is the trade name of the generic drug Rofecoxib. Vioxx was and is utilized, prescribed, provided and sold by physicians to patients such as Frank Newton Jones, Jr., also known as Frank N. Jones, for pain management and the relief of pain; Vioxx has been widely advertised and marketed by all named Defendants as a safe and effective pain relief medication.

- 21. Vioxx is a cycloosygenese-2 (Cox-2) specific inhibitor. Vioxx is a non-steroidal anti-inflammatory drug that exhibits anti-inflammatory, analgesic and anti-pyretic activities in animal models. The mechanism of action of Vioxx is believed to be due to inhibitors of prostaglandin synthesis via inhibition of Cox-2.
- 22. Vioxx has been widely advertised by the defendants as an effective pain reliever.
- 23. Ibuprofen is a widely used drug to reduce pain and inflammation.

  Ibuprofen sales are estimated to exceed \$10 billion per year. A major side effect of Ibuprofen is gastrointestinal in nature. Merck & Company, Inc. endeavored to develop a drug with pain relieving and anti-inflammatory qualities that would not harm the user's stomach. Merck & Company, Inc. developed, tested and obtained FDA approval for Vioxx, a Cox-2 inhibitor designed to replace Ibuprofen.
- 24. Defendant Merck & Company, Inc. made filing(s) with the United States Food and Drug Administration in the United States with regard to Vioxx.
- 25. These drugs, developed, tested and distributed by Defendant Merck & Company, Inc., have been linked to several severe and life threatening medical

disorders including, but not limited to, edema, changes in blood pressure, heart attack, stroke, seizures, kidney and liver damage, pregnancy complications and death.

26. Evidence linking the subject drug formulations to significant edema, serious cardiovascular events, and death has been noted and reported in a large study that was sponsored by Merck & Company, Inc. in 2000. These known material risks were not disclosed to or shared with Plaintiffs by any Defendant.

27. Defendants' strategy beginning in the 1990's has been to aggressively market and sell these products by falsely misleading potential users about the products and by failing to protect users from serious dangers which Defendant knew or should have known would result from use of these products.

28. Defendants widely and successfully marketed Vioxx in the United States by undertaking an advertising blitz extolling the virtues of Vioxx in order to induce widespread use of the products. The marketing campaign consisted of advertisements, promotional literature to be placed in the offices of doctors and other healthcare providers, and other promotional materials provided to potential Vioxx users.

29. The advertising program, as a whole, sought to create the image, impression and belief by consumers and physicians that the use of Vioxx was safe for human use, had fewer side effects and adverse reactions than other pain relief medications and would not interfere with daily life, even though the Defendants knew

these representations to be false, and even though the defendants had no reasonable grounds to believe them to be true.

disregard of the consequences to individuals such as Plaintiffs, concealed, downplayed and understated the health hazards and risks associated with Vioxx.

Defendants, through promotional literature, and direct contact with doctors by their sales representatives in Hawaii, deceived and/or lulled potential users of Vioxx by relaying positive information, including testimonials from satisfied users, and manipulated statistics to suggest widespread acceptability, while concealing and/or downplaying the known adverse and serious health effects. Defendants concealed material relevant information from potential Vioxx users and minimized user and prescriber concern regarding the safety of Vioxx.

31. In particular, in the materials produced by Defendants, Defendants falsely misrepresented the severity, frequency and nature of adverse health effects caused by Vioxx, and falsely represented that adequate testing had been conducted concerning Vioxx.

32. As a result of the Defendants' advertising and marketing efforts, and representations concerning the subject products, the drugs are pervasively prescribed throughout the United States.

#### FIRST CLAIM FOR RELIEF

(Strict Liability - Failure to Warn - Defendant Merck & Company, Inc.; Doe Defendant Pharmaceutical Company Defendants; and Doe Defendant Pharmacies)

33. Plaintiffs incorporate by reference herein paragraphs 1 through 32 as though fully set forth herein.

34. The drug products previously described was defective as the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution, in that, and not by way of limitation, said products and their warnings, instructions and directions failed to warn of the dangerous propensities of said products, which risks were known or reasonably scientifically knowable to Defendants. The Defendants, and each of them, knew or should have known of the defective condition, characteristics and risks associated with said products, as previously set forth herein.

35. At all times herein mentioned, the aforementioned product was defective, and Defendants, and each of them, knew that the product was to be used by the user without inspection for defects therein. Moreover, Plaintiffs neither knew, nor had reason to know at the time of the use of the subject products, of the existence of the aforementioned defects.

36. As a result of the defective condition of the aforementioned product,
Plaintiffs suffered injuries and damages as alleged herein.

# SECOND CLAIM FOR RELIEF

(Negligence - All Defendants)

37. Plaintiffs incorporate by reference herein Paragraphs 1 through 36 as though fully set forth herein.

38. At all times herein mentioned, Defendants, and each of them, had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, prepare for use, sell, prescribe and adequately warn of the risks and dangers of the aforementioned product.

39. At all times herein mentioned, Defendants, and each of them, negligently and carelessly manufactured, designed, formulated, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold the aforementioned products and failed to adequately test and warn of the risks and dangers of the aforementioned products.

40. As a result of said negligence and carelessness of the defendants and each of them, Plaintiff suffered injuries and damages as alleged herein.

#### THIRD CLAIM FOR RELIEF

(Negligence Per Se - Merck & Company, Inc.; Doe Pharmaceutical Company Defendants)

41. Plaintiffs incorporate by reference herein Paragraphs 1 through 40 as though fully set forth herein.

42. At all times herein mentioned, Defendants, and each of them, had an obligation not to violate the law, in the manufacture, design, formulation, compounding, testing, production, processing, assembly, inspection, research, distribution, marketing, labeling, packaging, preparation for use, sale and warning of the risks and dangers of the aforementioned products.

43. At all times herein mentioned, Defendants, and each of them, violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 301, et seq., related amendments and codes and federal regulations provided thereunder, the Sherman Food, Drug and Cosmetic Law, Hawaii Revised Statutes Chapter 328, 481A and section 480-2 as alleged more specifically hereinafter, and regulations promulgated thereunder, and other applicable laws, statutes and regulations.

44. Frank Newton Jones, Jr., also known as Frank N. Jones, as a purchaser and consumer of the products, is within the class of persons the statutes and regulations described above are designed to protect, and his death is the type of harm these statues are designed to prevent.

45. Defendants failed to meet the standard of care set by the following statutes and regulations, which were intended for the benefit of individuals such as Plaintiffs, making Defendants negligent per se:

a. The labeling lacked adequate information on the use of Vioxx, even though the Defendants were aware of the widespread use of the Vioxx. (21 C.F.R. Section 201.56(a) and (d))

- b. The labeling lacked adequate information on the approximate kind, degree and duration of expected improvement alone or in combination in violation of 21 C.F.R. Section 201.57(c)(3)(i).
- c. The labeling did not state that there was a lack of evidence to support the common belief of the safety and efficacy of Vioxx (21 C.F.R. 201.57(c)(3)(i) and (iv) and (c)(2))
- d. The labeling failed to add warnings for serious cardiovascular events and death as soon as there was reasonable evidence of their association with the drug. (21 C.F.R. 201.57(c).
- e. There was inadequate information for patients for the safe and effective use of Defendants' drugs, in violation of 21 C.F.R. 201.57(f)(2).
- f. There was inadequate information regarding special care to be exercised by the doctor for safe and effective use of Defendants' drugs in violation of 21 C.F.R. 201.57(f)(1).
- g. The labeling was misleading and promotion violation of 21 C.F.R.201.56(b).
- h. The labeling was misleading in violation of Hawaii Revised Statutes,
  Chapter 328, including but not limited to Sections 328-3, Section 328-6, and Section 328-15.

i. Defendants' advertising and representations regarding the subject drug product were false and misleading in violation of Hawaii Revised Statutes, Chapter 328 including but not limited to Sections 328-3, 328-6, 328-17(e) and 328-20.

46. As a result of the violations of the statutes described above, Plaintiffs suffered the injuries and damages as alleged herein.

# FOURTH CLAIM FOR RELIEF

(Breach of Implied Warranty - Merck & Company, Inc., DOE Pharmaceutical Company Defendants)

- 47. Plaintiffs incorporate by reference herein Paragraphs 1 through 46 as though fully set forth herein.
- 48. Prior to the time that the aforementioned products were used by Plaintiff, Defendants, and each of the, impliedly warranted to Plaintiffs and Plaintiffs' agents and physicians that said products were of merchantable quality and safe and fit for the use for which they were intended.
- 49. Plaintiffs were and are unskilled in the research, design and manufacture of the aforementioned products and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using the aforementioned products.
- 50. The aforementioned products were neither safe for their intended use nor of merchantable quality, as impliedly warranted by Defendants, in that they had

dangerous propensities when put to their intended use and would cause severe injuries to the user.

51. As a result of the aforementioned breach of implied warranties by the defendants and each of them, Plaintiffs suffered injuries and damages as alleged herein.

#### FIFTH CLAIM FOR RELIEF

(Breach of Express Warranty - Merck & company, Inc., and Doe Pharmaceutical Company Defendants)

- 52. Plaintiffs incorporate by reference herein Paragraphs 1 through 51 as though fully set forth herein.
- 53. At all times herein mentioned, Defendants expressly warranted to Plaintiffs and Plaintiffs' agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned products were safe, effective, fit and proper for their intended use.
- 54. In utilizing the aforementioned products, Plaintiffs relied on the skill, judgment, representations and foregoing express warranties of the Defendants, and each of them. Said warranties and representations were false in that the aforementioned products were not safe and were unlit for the uses for which they were intended.

55. As a result of the foregoing breach of express warranties by the Defendants, and each of them, Plaintiff suffered injuries and damages as alleged herein.

# SIXTH CLAIM FOR RELIEF

(Deceit by Concealment - Defendant Merck & Company, Inc., Pharmaceutical Company Defendants Does 1 through 50, and Defendant Pharmacy Does 51 through 100)

56. Plaintiffs incorporate by reference herein Paragraphs 1 through 55 as though fully set forth herein.

57. Defendants, and each of them, from the time that the aforementioned products were first manufactured, marketed and distributed, and up to the present, willfully deceived Plaintiffs by concealing from the Plaintiff, Plaintiffs' physicians and the general public, the true facts concerning said pharmaceutical products, which the Defendants, as manufacturers, makers and distributors of the products, had a duty to disclose.

58. As set forth above, Defendant Merck & Company, Inc. sponsored a large study which concluded that patients taking Vioxx had four times the risk of heart attacks and that the risk appears to increase over time.

59. As set forth above, Defendant Merck & Co., Inc. received letters from the United States Department of Health and Human Services in December of 1999 stating that it had been determined that the promotional literature utilized by Defendant Merck & Co., Inc. were false and misleading because they contained

misrepresentations of Yioxx's safety profile, unsubstantiated comparative claims, and were lacking in fair balance.

60. At all times herein mentioned, Defendants, and each of them, conducted a sales and marketing campaign to promote the sale of the aforementioned drug products and willfully deceive Plaintiffs, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the aforementioned products. Defendants, and each of them, were aware of the foregoing, and that the aforementioned products were not safe, fit and effective for human consumption, the use of said products is hazardous to health, and said products have a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiffs.

61. The Defendants intentionally concealed and suppressed the true facts concerning said pharmaceutical products with the intent to defraud Plaintiffs, in that the Defendants knew that Plaintiff's physicians would not prescribe the subject products, and Plaintiffs would not have used the subject products, if they were aware of the true facts concerning the dangers of subject products.

62. As a result of the foregoing fraudulent and deceitful conduct by the Defendants and each of them, Plaintiffs suffered injuries and damages as alleged herein.

#### SEVENTH CLAIM FOR RELIEF

(Negligent Misrepresentation Defendant Merck & Company, Inc.; Doe Defendant Pharmaceutical Company Defendants; and Doe Defendant Pharmacies)

- 63. Plaintiff incorporates by reference herein Paragraphs 1 through 62 as though fully set forth herein.
- 64. Defendants, and each of them, from the time that the aforementioned products were first manufactured, marketed and distributed, and up to the present, made false misrepresentations, as previously set forth herein, to Plaintiffs, Plaintiffs' physicians and the general public, including but not limited to the misrepresentation that said pharmaceutical product was safe, fit and effective for human consumption. At all times herein mentioned, Defendants, and each of them, conducted a sales and marketing campaign to promote the sale of the aforementioned drug products and willfully deceive Plaintiffs, Plaintiffs' physicians and the general public as to the health risks and consequences of the use of the aforementioned products.
- 65. The Defendants made the foregoing false representations without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of said Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject products.

66. The foregoing representations by the Defendants, and each of them, were in fact false, in that the aforementioned products were not safe, fit and effective for human consumption, the use of said products is hazardous to health, and said products have a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiffs as delineated herein.

67. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of the subject products.

68. In reliance on the misrepresentations by the Defendants, and each of them, Plaintiffs were induced to purchase and use the aforementioned products. If Plaintiffs had known of the true facts and the facts concealed by the Defendants, Plaintiffs would not have used the subject products. The reliance of Plaintiffs upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities who were in a position to know the true facts.

69. As a result of the foregoing negligent misrepresentations by the Defendants, and each of them, Plaintiffs suffered injuries and damage as alleged herein.

#### EIGHTH CLAIM FOR RELIEF

(Violation of the <u>Uniform Deceptive Trade Practices Act</u>, Chapter 481A, Hawaii Revised Statutes - Defendant Merck & Company, Inc.; Doe Defendant Pharmaceutical Company Defendants; and Doe Defendant Pharmacies)

70. Plaintiffs incorporate and reference herein Paragraphs 1 through 69 as though fully set-forth herein.

71. Plaintiffs bring this cause of action pursuant to the <u>Uniform Deceptive</u>

<u>Trade Practices Act</u>, Chapter 481A, Hawaii Revised Statutes, as a representative action and Plaintiffs respectfully request that the Court award all appropriate remedies provided by the statute and/or in the prayer.

- 72. The <u>Uniform Deceptive Trade Practices Act</u>, Chapter 481A-3, Hawaii Revised Statutes provides that a deceptive trade practice occurs when the person or company:
  - (5) Represents that goods or services have sponsorship, approval characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;
  - (12) Engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.
- 73. The acts and practices described in Paragraphs 1 through 67 above, were and are likely to mislead the general public and therefore constitute unfair business practices within the meaning of Chapter 481A, Hawaii Revised Statutes. The acts of untrue and misleading advertising set forth in preceding paragraphs are incorporated by reference and are, by definition, violations of Chapters 481A. This conduct includes, but is not limited to:
  - a. Representing to Plaintiffs, Plaintiffs' physicians and the general public that said pharmaceutical products were safe, fit and effective for human

consumption, knowing that said representations were false, and concealing from the Plaintiffs, Plaintiffs' physicians and the general public that said products had a serious propensity to cause injuries to users;

- b. Engaging in advertising programs designed to create the image, impression and belief by consumers and physicians that the use of Vioxx was safe for human use, had fewer side effects and adverse reactions than other pain medications, constituted a convenient, safe form of pain relief and would not interfere with daily life, even though the Defendants knew these misrepresentations to be false, and even though the Defendants had no reasonable grounds to believe them to be true;
- c. Purposely downplaying and understating the health hazards and risks associated with Vioxx;
- d. Issuing promotional literature deceiving potential users of Vioxx by relaying positive information, including testimonials from satisfied users, and manipulating statistics to suggest widespread acceptability, while downplaying the known adverse and serious health effects and concealing material relevant information regarding the safety of said products.

74. The unlawful, unfair and fraudulent business practices of Defendants described herein present a continuing threat to members of the public in that Defendants continue to engage in the conduct described therein.

75. As a result of their conduct described above Defendants have been and will be unjustly enriched. Specifically, Defendants have been unjustly enriched by receipt of hundreds of millions of dollars in ill-gotten revenues from the sale and prescription of said drugs in Hawaii and elsewhere, sold in large part as a result of the acts and omissions described herein.

76. Because of the fraudulent misrepresentations made by Defendants as detailed above, and the inherently unfair practice of committing a fraud against the public by intentionally misrepresenting and concealing material information, the acts of Defendants described herein constitute unfair or fraudulent business practices.

77. Plaintiff seeks and order of this court compelling the Defendants to provide restitution, assessing Defendants treble damages as well as ordering them to pay all of Plaintiffs costs of suit, including attorneys fees, and to disgorge the monies collected and profits realized by Defendants, and each of them, as a result of their unfair business practices, and injunctive relief ordering Defendants, and each of them, to cease such unfair business practices in the future.

#### NINTH CLAIM FOR RELIEF

(Violation of Hawaii Revised Statutes, Section 480-2- Defendant Merck & Company, Inc.; Doe Defendant Pharmaceutical Company Defendants; and Doe Defendant Pharmacies)

78. Plaintiffs incorporate and reference herein Paragraphs 1 through 77 as though fully set forth herein.

79. Plaintiffs bring this cause of action pursuant to Section 480-2, Hawaii Revised Statutes, as a representative action or as a class action.

- 80. Section 480-2 provides that it is unlawful for any person, firm, corporation or association to use unfair or deceptive acts or practices in the conduct of any trade or commerce.
- 81. At all times herein mentioned Defendants have committed acts of disseminating untrue and misleading statements as defined by Hawaii Revised

  Statutes, Sections 480-2 by engaging in the following acts and practices with intent to induce members of the public to purchase and use Pain medication:
  - a. Representing to Plaintiffs, Plaintiffs' physicians and the general public that said pharmaceutical products were safe, fit and effective for human consumption, knowing that said representations were false, and concealing from the Plaintiffs. Plaintiffs' physicians and the general public that said products had a serious propensity to cause injuries to users;
  - b. Engaging in advertising programs designed to create the image, impression and belief by consumers, physicians that the use of Vioxx was safe for human use, had fewer side effects and adverse reactions than other pain medication, constituted a convenient, safe form of pain relief

and would not interfere with daily life, even though the Defendants knew these to be false, and even though the defendants had no reasonable grounds to believe them to be true;

- c. Purposely downplaying and understating the health hazards and risks associated with Vioxx;
- d. Issuing promotional literature deceiving potential users of Vioxx by relaying positive information, including testimonials from satisfied users, and manipulating statistics to suggest widespread acceptability, while downplaying the known adverse and serious health effects and concealing material relevant information regarding the safety of said products.
- 82. The foregoing practices constitute false and misleading conduct within the meaning of Hawaii Revised Statutes, Section 480-2.
- 83. The acts of untrue and misleading statements by Defendants described herein above present a continuing threat to members of the public in that the acts alleged herein are continuous and ongoing, and the public will continue to suffer the harm alleged herein.
- 84. As a result of their false and misleading statements described above, Defendants have been and will be unjustly enriched. Specifically, Defendants have been unjustly enriched by hundreds of millions of dollars in ill-gotten gains from the

sale and prescription of Vioxx, sold in large part as a result of the false or misleading statements described herein.

85. Plaintiffs seek an order of this court compelling the Defendants to provide restitution, and to disgorge the monies collected and profits realized by Defendant, and each of them, as a result of their unfair business practices, and injunctive relief calling for Defendants, and each of them, to cease such unfair business practices in the future.

86. Plaintiffs seek the imposition of a constructive trust over, and restitution and disgorgement of, monies collected and profits realized by Defendants, and each of them, to cease such false and misleading advertising in the future.

# TENTH CLAIM FOR RELIEF (Punitive Claim)

87. Plaintiffs incorporate and reference herein Paragraphs 1 through 86 as though fully set forth herein.

and/or undertaken recklessly and/or wantonly and/or in a grossly negligent manner and/or with a conscious and/or reckless disregard and/or indifference to the consequences and/or amounting to a criminal indifference to the consequences and/or with a conscious and/or reckless disregard for the rights, feelings and sensitivities of Plaintiffs and the deceased, Frank Newton Jones, Jr., also known as Frank N. Jones, justifying the imposition of punitive damages against Defendants and each of them as provided by law in amounts to be determined at trial.

# ELEVENTH CLAIM FOR RELIEF

89. Plaintiffs incorporate and reference herein Paragraphs 1 through 88 as though fully set forth herein.

90. As a direct and proximate result of the negligence and carelessness of Defendants as aforesaid, which resulted in the death of Mr. Jones, Plaintiff Donna Meifert Jones, individually, has suffered and will continue to suffer the loss of society, companionship, comfort, care, attention, advice, counsel, support, consortium, familial relations, love, affection and services (including, but not limited to, household services) of her husband, Mr. Jones, for which said Plaintiff is entitled to recover damages against Defendants in amounts as shall be proved at trial.

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, jointly and severally, as follows:

- 1. For past and future general damages, according to proof;
- 2. For past and future medical and incidental expenses, according to proof;
- For past and future loss of earnings and/or earning capacity, according to proof;
- 4. For punitive and exemplary damages in an amount to be determined at trial.
- 5. For prejudgment interest on all damages as is allowed by the laws of the State of Hawaii;
- 6. For past and future mental and emotional distress, according to proof;

- 7. For past and future loss of consortium according to proof;
- 8. For past and future costs of suit incurred herein;
- 9. For injunctive relief, enjoining Defendants from the acts of unfair competition and untrue and misleading advertising.
- 10. For such other and further relief as the Court deems just and proper.
- 11. That Plaintiffs be awarded their costs and expenses, including reasonable attorneys' fees and prejudgment interest commencing

  November 25, 1999, at the rate prescribed by Hawaii statute.

DATED: Honolulu, Hawaii, November 23, 2001.

WAYNE D. PARSONS
Attorney for Plaintiffs